K052535

OCT 2 1 2005

510(k) Summary
for
VERIFY® SPI Chemical Indicator

1. SUBMITTER NAME AND ADDRESS

Richard Bancroft
Albert Browne Ltd., a Subsidiary of STERIS Corporation
Chancery House
190 Waterside Road
Hamilton Industrial Park
Leicester LE5 1QZ
United Kingdom

Contact: Richard Bancroft
Telephone number: 44 116 276 8636

2. DEVICE NAME

Proprietary Name: VERIFY® SPI Chemical Indicator
Common/Usual Name: SPI Chemical Indicator
Classification Name: Physical/Chemical Sterilization Process Indicator

3. PREDICATE DEVICES

- STERIS PROCESS™ Chemical Monitor (K921559, STERIS Corporation)
- 3M™ Comply™ 1249 Liquid Peracetic Acid Chemical Indicator (K000355, 3M Health Care)

4. INTENDED USE

The VERIFY® SPI Chemical Indicator (SPI Chemical Indicator) is a peracetic acid concentration indicator for routine monitoring of the STERIS SYSTEM 1® Sterile Processing System employing STERIS 20™ Sterilant Concentrate.

The SPI Chemical Indicator is dedicated for use in the STERIS SYSTEM 1® Processing System employing STERIS 20™ Sterilant Concentrate.

5. DEVICE DESCRIPTION

The SPI Chemical Indicator is a single-use chemical indicator consisting of a polypropylene strip with indicator ink printed on one end. The SPI Chemical Indicator was developed to monitor the peracetic acid concentration of the STERIS 20™ Sterilant at the point of use in a STERIS SYSTEM 1® Processor during a processing cycle. The SPI Chemical Indicator was formulated to undergo a color change from purple to white at peracetic acid concentrations of ≥1800 ppm.

6. TECHNOLOGICAL CHARACTERISTICS

The technological characteristics of the predicates, STERIS PROCESS™ Chemical Monitor and 3M™ Comply™ 1249 Liquid Peracetic Acid Chemical Indicator, are similar to that of the SPI Chemical Indicator described in this submission. Both the STERIS Process Chemical Monitor and SPI Chemical Indicator are non-sterile, disposable polymeric strips containing an indicator square that change color in a STERIS SYSTEM 1® Processor cycle.

7. PERFORMANCE TESTING

Performance testing was conducted to demonstrate that the SPI Chemical Indicator is an effective monitor for the initial peracetic acid concentration of the use dilution of STERIS 20™ Sterilant Concentrate during a STERIS SYSTEM 1® Processor cycle.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 1 2005

Albert Browne Limited
C/O Cynthia J.M. Nolte, Ph.D., RAC
Senior Staff Consultant
Medical Devices Consultants
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K052535
Trade/Device Name: VERIFY® SPI CHEMICAL INDICATOR
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: II
Product Code: JOJ
Dated: September 14, 2005
Received: September 15, 2005

Dear Dr. Nolte:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K052535

Device Name: VERIFY® SPI Chemical Indicator

Indications for Use:

The VERIFY® SPI Chemical Indicator (SPI Chemical Indicator) is a peracetic acid concentration indicator that is used for routine monitoring of the STERIS SYSTEM 1® Sterile Processing System employing STERIS 20™ Sterilant Concentrate. The SPI Chemical Indicator changes color from purple to white when exposed to STERIS 20™ Sterilant Concentrate.

The SPI Chemical Indicator is dedicated for use in the STERIS SYSTEM 1® Processing System employing STERIS 20™ Sterilant Concentrate.

Prescription Use _____ AND/OR Over-The-Counter Use__x_
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Pat A for Sheila Murphy 10/20/05
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K052535